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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,868	06/16/2005	Dennis J Slamon	023070-129910US	6420
20350 7590 10/05/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER UNGAR, SUSAN NMN	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,868

Applicant(s)

SLAMON ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 December 1995.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1-31 are pending in the application and are currently under prosecution.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group 1, claims 1-11 and 13 are drawn to a method for determining the presence or absence of a colorectal cancer cell/diagnosing colorectal cancer as contemplated in the specification comprising determining the level of a target nucleic acid that encodes SEQ ID NO:2 in a biological sample from the patient.

Group 2, claims 1-12 are drawn to a method for determining the presence or absence of a colorectal cancer cell/determining the efficacy of treatment as contemplated in the specification comprising determining the level of a target nucleic acid that encodes SEQ ID NO:2 in a biological sample from the patient.

Group 3, claim 14-16 are drawn to an expression vector, host cell comprising a nucleic acid sequence that encodes SEQ ID NO:2.

Group 4, claims 17-in-part, 18-24, 26 are drawn to a method for determining the presence or absence of a colorectal cancer cell/diagnosing colorectal cancer as contemplated in the specification comprising determining the level SEQ ID NO:2 in a biological sample from the patient.

Group 5, claims 17-in-part, 18-25 are drawn to a method for determining the presence or absence of a colorectal cancer cell/determining the efficacy of treatment as contemplated in the specification comprising determining the level of SEQ ID NO:2 in a biological sample from the patient.

Group 6, claims 27-28 both in-part drawn to a method for treating cancer comprising administering an inhibitor of 26#77 gene product/anti-sense RNA.

Group 7, claims 27-28 both in-part drawn to a method for treating cancer comprising administering an inhibitor of 26#77 gene product/inhibitory RNA molecule.

Groups 8-20, claim 29-in-part, is drawn to 13 inventions drawn to a method for determining the presence or absence of a colorectal cancer cell/diagnosing colorectal cancer as contemplated in the specification comprising determining the level of a target nucleic acid that encodes a protein selected from the group consisting of SEQ ID NO:4,6,8,10, 12, 14, 16, 18, 20, 22, 24, 26, 28 in a biological sample from the patient.

Groups 21-33, claim 29-in-part, is drawn to 13 inventions drawn to a method for determining the presence or absence of a colorectal cancer cell/ determining the efficacy of treatment as contemplated in the specification comprising determining the level of a target nucleic acid that encodes a protein selected from the group consisting of SEQ ID NO:4,6,8,10, 12, 14, 16, 18, 20, 22, 24, 26, 28 in a biological sample from the patient.

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Groups 34-46, claim 30-in-part, is drawn to 13 inventions drawn to a method for determining the presence or absence of a colorectal cancer cell/diagnosing colorectal cancer as contemplated in the specification comprising determining the level of a protein selected from the group consisting of SEQ ID NO:4,6,8,10, 12, 14, 16, 18, 20, 22, 24, 26, 28 in a biological sample from the patient.

Groups 47-59, claim 30-in-part, is drawn to 13 inventions drawn to a method for determining the presence or absence of a colorectal cancer cell/ determining the efficacy of treatment as contemplated in the specification comprising determining the level of a protein selected from the group consisting of SEQ ID NO:4,6,8,10, 12, 14, 16, 18, 20, 22, 24, 26, 28 in a biological sample from the patient.

Groups 60-72, claim 31-in-part is drawn to 13 inventions drawn to a method for treating a cancer that overexpresses CPNE 1, ITGB4BP, RAE1, BMP7, GNAS, EIF2S2, DNCL2A, PSMA7, ADNP, C20 orf129, C20orf52, C20orf20, X20ofr188 gene product comprising administering to a subject in need of such treatment a therapeutically effective amount of an inhibitor of the expressed RNA, as contemplated in the specification, of CPNE 1, ITGB4BP, RAE1, BMP7, GNAS, EIF2S2, DNCL2A, PSMA7, ADNP, C20 orf129, C20orf52, C20orf20.

Groups 73-85, claim 31-in-part is drawn to 13 inventions drawn to a method for treating a cancer that overexpresses CPNE 1, ITGB4BP, RAE1, BMP7, GNAS, EIF2S2, DNCL2A, PSMA7, ADNP, C20 orf129, C20orf52, C20orf20, X20ofr188 gene product comprising administering to a subject in need of such treatment a therapeutically effective amount of an inhibitor of the expressed protein, as contemplated in the specification, of CPNE 1, ITGB4BP, RAE1, BMP7, GNAS, EIF2S2, DNCL2A, PSMA7, ADNP, C20 orf129, C20orf52, C20orf20.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and

(d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group I, forms a single general inventive concept comprising a method for determining the presence or absence of a colorectal cancer cell/diagnosing colorectal cancer as contemplated in the specification comprising determining the level of a target nucleic acid that encodes SEQ ID NO:2 in a biological sample from the patient.

Groups 2-85 are drawn to methods different from that of Group 1 and a product which is not used in the method of Group 1. Given that the claims are all drawn to methods different from Group 1 and a product not used in the method of Group 1, the additional claimed methods and product claimed do not meet the requirement for categories considered to have unity of invention.

For these reasons the claimed inventions are not so linked as to form a single general inventive concept and all methods are properly broken out as separate groups.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898.. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Ungar
Primary Patent Examiner
September 27, 2007

